REMARKS

Claims 4-5 and 8-16 are presently pending. Claim 11 has been allowed in a previous office action. Claim 11 has been amended to correct a typographical error. Thus, claims 4-5 and 8-16 remain pending in this application.

Claim Rejections - 35 U.S.C. § 103

Claims 4-5, 8-10, and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,828,716 to McEwan et al. ("McEwan") in view of U.S. Patent No. 6,074,883 to Kelly et al. ("Kelly").

Independent Claims 4 and 5

Independent claims 4 and 5 are directed toward a method of collecting and separating a patient's blood and recovering a platelet-rich concentrate. The methods include collecting a patient's blood using "a needle set comprising a hollow needle having attached tubing and a fitting adapted to engage a first port in an elongated container fitted with a movable plunger having a second port therein." The blood is centrifuged and separated into platelet-rich plasma and red blood cells, which are displaced by moving the plunger towards the first port and expelling the red blood cells into a waste bag through tubing attached to the first port. Platelet-poor plasma is separated by moving the plunger toward the first port and expelling the platelet-poor plasma through the third port of a plunger rod. Claim 4 differs from claim 5 in that claim 4 includes a first centrifuging step for separating red blood cells from platelet-rich plasma and a second centrifuging step for separating platelet-poor plasma from platelet-rich concentrate.

The Applicants respectfully submit that a *prima facie* case of obviousness has not been established because the cited references, either alone or in combination, do not disclose, teach, or suggest, several elements of claims 4 and 5.

A. McEwan and Kelly Lack "a needle set comprising a hollow needle having attached tubing and a fitting", as Required by the Methods of Claims 4 and 5

Neither McEwan nor Kelly discloses, teaches, or suggests a "needle set comprising a hollow needle having attached tubing and a fitting adapted to engage" an elongated container, as recited in claims 4 and 5. The Office Action relies upon McEwan in finding that this element is obvious. The needle 36 of McEwan, however, does not include "a **fitting** adapted to engage a first port in an

elongated container". Rather, the needle 36 of McEwan adds drawn blood directly into the blood sample collection chamber through a cap assembly. McEwan, FIG. 1b; col. 8, ll. 12-15. Thus, the needle of McEwan would have no use for tubing or a fitting. Likewise, while the Office Action does not rely upon Kelly in alleging that this element is obvious, no such needle set is disclosed in Kelly.

These reasons alone render claims 4 and 5 allowable.

B. McEwan and Kelly Lack "a movable plunger having a second port therein"

Furthermore, the cited references do not disclose an elongated container having **a first port** and having a **movable plunger** including **a second port**. The assembly of McEwan, which the Office Action at page 3 concedes lacks a movable plunger, includes only a single port 32, as shown in FIGs. 1a-1g. A second port as defined in the claims is not disclosed, taught, or suggested in McEwan. The Office Action suggests that Kelly discloses a movable plunger having a second port. Office Action, p. 3. In doing so, the Office Action mistakenly equates the carrier tube 102 of Kelly with the movable plunger of claims 4 and 5. The carrier tube 102 of Kelly, however, is merely a cylindrical tube (as best shown in FIGs. 1 and 5-6) adapted to attach to the bottom plug 110 and the top collar 112 and adapted to house the capillary tube 114. The operation of the carrier tube 102 is described only with reference to the cap 104 of the carrier tube 102 moving into the capillary tube 114 to create a seal to prevent blood or air to flow out. Kelly, col. 8, l. 36 - col. 9, l. 66. Nowhere does Kelly disclose using the carrier tube 102 as a plunger or even that the carrier tube 102 is movable. Thus, Kelly does not disclose nor suggest using the carrier tube 102 to remove separated components, as required by claims 4 and 5, let alone doing so **two separate times** to remove red blood cells and platelet-poor plasma after **two separate** centrifuge process as required by claim 4. Further, in view of the fact that Kelly only discloses analyzing separated components **remaining within** the capillary tube 114 via an optical reading device (*id.*, col. 6, ll. 10-15; col. 10, ll. 32-43), it seems unlikely – if not impossible – that the carrier tube 102 would be capable of being used as a plunger for removing separated components of the blood from the capillary tube 114. Finally, Kelly's carrier tube 102 does not have a port associated therewith, as does the movable plunger of claims 4 and 5.

McEwan and Kelly lacking this element is yet another reason why claims 4 and 5 are allowable.

C. McEwan and Kelly Lack the Acts of "moving said plunger towards said first port and expelling said red blood cells into a waste bag"

In addition, the non-cellular component in McEwan is not displaced "**by moving said plunger** towards said first port and expelling said red blood cells into **a waste bag**," as recited in claims 4 and 5. Even assuming, *arguendo*, that the Office Action's statement that "it would have been an obvious step . . . to choose to decant separated blood cells into a bag" were true, the methods of doing so – by moving a plunger toward a first port – would not be obvious. This claim element is likewise not disclosed, taught, or suggested by Kelly.

This is a further independent basis for the allowability of claims 4 and 5.

D. McEwan and Kelly Lack the Second Centrifuging Act of Claim 4

Additionally, the cited references do not disclose a second centrifuging act wherein platelet-rich concentrate is separated from platelet-poor concentrate, as in claim 4. The Office Action relies upon column 14, lines 43-51 of McEwan in stating that "McEwan also teaches that the components may be further separated by centrifugation until desired separation is achieved." Office Action, p. 3. This cited portion of McEwan, however, only refers to separation of the "lower density component" from the "denser cellular component." McEwan, col. 14, ll. 46-49. The lighter, low density, non-cellular component is defined by McEwan as serum or plasma while the denser cellular component contains blood cells. *Id.*, col. 11, ll. 25-30. In other words, this statement in McEwan simply refers to separating platelet-rich plasma from red blood cells. Thus, McEwan does **not** disclose "centrifuging said platelet-rich plasma remaining in said container and separating a platelet-rich concentrate from a platelet-poor plasma", as recited in claim 4. Furthermore, the combination of Kelly and McEwan would only separate the blood into serum and cellular material and therefore not anticipate the separation of platelet concentrate from the serum or plasma, as in claims 4 and 5.

E. McEwan and Kelly Lack the Act of "attaching a hollow plunger rod having a third port therein to said plunger and displacing the platelet-poor plasma"

The cited references do not disclose "attaching a hollow plunger rod having a third port therein to said plunger and displacing the platelet-poor plasma" by expelling the platelet-poor plasma "through the third port" of the plunger rod, as recited by claims 4 and 5. The Office Action analogizes the end 118 of the capillary tube 114 of Kelly to the hollow plunger rod of claim 4.

However, the capillary tube 114 of Kelly does not include a third port, through which platelet-poor plasma is expelled into a waste bag. Thus, this element is also not disclosed by McEwan, Kelly, or a combination thereof.

This is yet another reason that claims 4 and 5 are allowable.

For at least these **five** reasons, independent claims 4 and 5 are allowable over Kelly and McEwan. Claims 8-10 and 12-15, which depend from either claim 4 or 5, are allowable for at least the same reasons.

Independent Claim 16

Independent claim 16 is directed toward a method of collecting and separating a patient's blood and recovering a platelet-rich concentrate. The method includes collecting blood using "a needle set comprising a hollow needle and a fitting adapted to engage a first port in a container fitted with a movable plunger having a second port therein." The blood is centrifuged and separated into platelet-rich plasma and red blood cells, which are displaced by moving the plunger towards the first port and expelling the red blood cells through the first port. The platelet-rich plasma is centrifuged to separate a platelet-rich concentrate from a platelet-poor plasma. A hollow plunger rod having a third port therein is attached to the plunger to displace the platelet-poor plasma from the container "by moving said plunger towards said first port and expelling said platelet-poor plasma through said second port of said plunger and said third port of said plunger rod".

Claim 16 includes many of the claim elements of claims 4 and 5 discussed above, including the following:

- "a needle set comprising a hollow needle and a fitting adapted to engage a first port";
- "a movable plunger having a second port therein";
- "displacing the red blood cells from said container by moving said plunger towards said first port and expelling said red cells through said first port";
- A second centrifuging act for "separating a platelet-rich concentrate from a platelet-poor plasma"; and
- "displacing the platelet-poor plasma from said container by moving said plunger towards said first port and expelling said platelet-poor plasma through . . . said third port of said plunger rod".

The Applicants respectfully submit that claim 16 is allowable because McEwan and Kelly lack these elements, as provided above with respect to claims 4 and 5.

Conclusion

It is the Applicants' belief that all of the claims are now in condition for allowance and action towards that effect is respectfully requested. The Applicants respectfully request that a timely Notice of Allowance be issued in this case. If there are any matters which may be resolved or clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney at the number indicated.

The Applicants note that the previous response filed on October 2, 2006 added a fourth independent claim, which was not reflected in the corresponding Amendment Transmittal Letter. The Applicants assume that, pursuant to the authorization provided in the Amendment Transmittal Letter, the proper fee was deducted from the Applicants' deposit account. However, if such deduction was not previously made, the Commissioner is authorized to deduct such fee and any other fee that may be required (except for payment of the issue fee) to Nixon Peabody, LLP, Deposit Account No. 50-4181, Order No. 247168-000158USD1. A duplicate copy of this paper is enclosed.

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Respectfully submitted,

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